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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/731,738

12/09/2003

Brian K. Shoichet

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08/14/2006

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EXAMINER

CHUNG, SUSANNAH LEE

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 08/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/731,738	<b>Applicant(s)</b> SHOICHET ET AL.	
	<b>Examiner</b> Susannah Chung	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 28-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 28-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

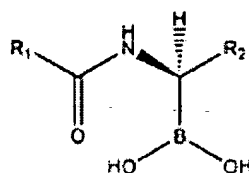
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|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

Claims 1-12 and 28-34 are pending in this application.

*Election of Species*

This application contains claims directed to the following patentably distinct species:



Claims 1-12 and 28-34 drawn to compounds of formula,

wherein  $R_1$  is a substituent selected from hydrogen, alkyl, alkenyl, cycloalkenyl, and heterocyclyl moieties; and wherein  $R_2$  is a substituent selected from heterocyclyl, cycloalkenyl, alkenyl and alkyl moieties.

The species are independent or distinct because of the numerous meanings of the variables cycloalkenyl and heterocyclyl, wherein

"Cycloalkenyl" means a structure containing one or more rings, each ring containing about 4 to about 10 carbon atoms and containing at least one double bond. Without limitation, one or more of the rings may be aromatic, thereby including an aryl (unsubstituted or substituted) moiety. In addition, one or more rings may be substituted by one or more functional groups. Representative cycloalkenyls include, but are not limited to, cyclohexadienyl, phenyl, biphenyl, naphthyl, and benzyl.

and

"Heterocyclyl" or "Heterocyclic ring" refers to an unsaturated or saturated, substituted or unsubstituted, mono or multicyclic about 4- through about 10-membered heterocyclic ring containing one or more heteroatoms including but not limited to oxygen, nitrogen or sulfur. Representative heterocyclyl moieties include, but are not limited to, pyridinyl, pyrazinyl, thiophenyl, thiophenyl-2-yl, thiophenyl-3-yl, pyrrolyl, furanyl, thiazolyl, imidazolyl, indazolyl, benzothiophenyl, isoindolyl and oxazolyl.

It is impossible to ascertain a meaningful for search and examination purposes.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

**Therefore, an election of species is required for search and examination purposes** including an exact definition of each substitution on the base molecule (formula of claim 1), wherein a single member at each substituent group or moiety is selected. For example, if a base molecule has a substituent group R<sub>1</sub>,

**wherein R<sub>1</sub> is a substituent selected from hydrogen, alkyl, alkenyl, cycloalkenyl, and heterocyclyl moieties**

then applicant must select a single substituent of R<sub>1</sub>, for example hydrogen, and each subsequent variable position, i.e. R<sub>2</sub>. In the instant case, upon election of a single compound, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar thereto as to be within the same inventive concept and reduction to practice). The scope of an independent invention will encompass all compounds within the scope of the claim, which fall into the same class and subclass as the elected compound, but may also include additional compounds, which fall in related subclasses. Examination will then proceed on the elected compound AND the entire scope of the invention encompassing the elected compound as defined by common classification. A clear statement of the examined invention, defined by those class(es) and subclass(es) will be set forth in the first action on the merits. Note that the election of species requirement will not be made final until such time as applicant is informed of the full scope of compounds along with (if appropriate) the process of using or making said compound under examination. This will be set forth by reference to specific class(es) and subclass(es) examined. Should applicant traverse on

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the ground that the compound are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the compound to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other.

All compounds falling outside the class(es) and subclass(es) of the selected compound and any other subclass encompassed by the election above will be directed to nonelected subject matter and will be withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R. 1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter. (The provisions of 35 U.S.C. 121 apply with regard to double patenting covering divisional applications.)

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

During a telephone conversation with Attorney Rodney DeKruif on 13 July 2006 a provisional election of species was made for search and examination purposes

where  $R_1$  is a thiophen-2-yl moiety and  $R_2$  is a phenyl moiety.

Affirmation of this election of species must be made by applicant in replying to this Office action.

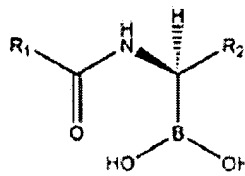
### *Claim Rejections - 35 USC § 102*

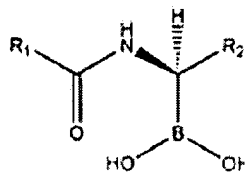
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Kinder, et al., “Acylamido boronic acids and difluoroborane analogs of amino acids,” J. Med. Chem., Vol. 28, pp. 1917-25, 1985.



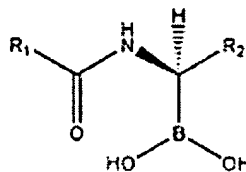
Applicants claims relate to compound of claim 1, , wherein R<sub>1</sub> and R<sub>2</sub> is cycloalkenyl or phenyl. Kinder discloses compounds that anticipate the instantly claimed genus wherein: **R<sub>1</sub>** and **R<sub>2</sub>** are phenyl. ((benzoylaminophenylmethyl) boronic acid, CAS RN 98541-61-8).

### *Scope of the Elected Invention*

Claims 1-12 and 28-34 are pending in this application.

The scope of the elected subject matter that will be examined and searched is as follows:

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Claims 1-12 and 28-34, compounds of formula, , depicted in claim

10, page 2, wherein R1 is heterocyclyl and R2 is phenyl or cycloalkenyl.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

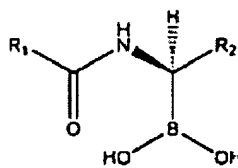
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12 and 28-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kinder et al., "Acylamido boronic acids and difluoroborane analogs of amino acids," J. Med. Chem., Vol. 28, pp. 1917-25, 1985.

Applicants instant elected invention teaches the compound having the formula,

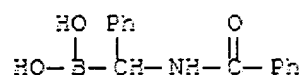


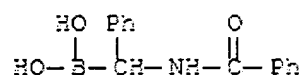
, depicted in claim 28, wherein R1 is thiophen-2-yl (elected), hydrogen,

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alkyl, alkenyl, cycloalkenyl or heterocyclyl moieties and **R2** is phenyl (elected), cycloalkenyl, alkenyl, alkyl, or heterocyclyl moieties. These products are used as inhibitors of  $\beta$ -Lactam antibiotics. (claim 34, page 6).

Determination of the scope and content of the prior art (MPEP § 2141.01)



Kinder teaches acyl amino boronic acids of formula, , a boronic acid inhibitor (see Figure 1, p. 1918; and Scheme III, intermediates IA-VA; and Experimental Section (Alkyl Boronic esters, p. 1922 and Acylamino Boronic esters, p. 1923).

Ascertainment of the difference between the prior art and the claims (MPEP § 2141.02)

The difference between the prior art of Kinder and the claims is that the instant application is broader in that it also includes heterocyclic moieties in addition to the aryl and alkyl moieties taught in Kinder.

Finding of prima facie obviousness – rationale and motivation (MPEP § 2142-2413)

One skilled in the art would have found the claimed compound prima facie obvious because the instantly claimed compound and the compound in Kinder share the same boronic acid core structure. The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (i.e. pharmacological use as antibiotics). Although, applicant's compound differs in that it encompasses a broader range of compounds, there is still overlap with the prior art of Kinder. In addition, both the instant application and Kinder use the same processes of making the compound of claim 1 (see instant specification, page 7, paragraph 3 where it discusses the general strategy employed in scheme 1 is from Matteson) and (Kinder, page 1918, column 1 states that the synthetic methods were patterned after those of Matteson). Finally, they are used



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for the same pharmacological use so one skilled in the art would expect the species would have similar properties as the genus.

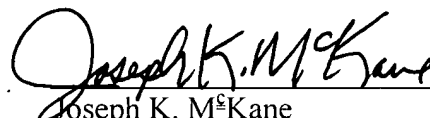
*Telephone Inquiry*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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AU 1626, Group 1620  
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Date: 01 August 2006